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3626

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In Re Application of:	)	
	)	
William M. Kleinfelter	)	Art Unit: 3626
	)	
Serial No.: 09/348,774	)	Examiner: Robert W. Morgan
	)	
Filed: July 7, 1999	)	Docket No.: 3207/22
	)	
For: **PRESCRIPTION DATA PROCESSING SYSTEM FOR DETERMINING NEW THERAPY STARTS**	)	Appeal No.: Not yet assigned

REPLY BRIEF UNDER 37 C.F.R. §1.193

Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

Sir:

This is a reply to the Examiner's Answer, dated March 9, 2004, submitted by Examiner Robert W. Morgan in connection with the above identified application ("the Application").

PROCEDURAL SUMMARY

In an Office Action dated December 2, 2002 (the "December Office Action"), the Examiner rejected claims 1-49 of the Application under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,950,630 to Portwood et al. (hereinafter "Portwood"). The Applicant subsequently appealed the rejections and filed an Appeal Brief on November 3, 2003 that raised arguments against the rejections including the following:

(A) Portwood fails to teach or suggest the first and second comparing elements of claim 1;

(B) Portwood fails to teach or suggest the identifying element of claim 1; and

(C) Portwood fails to teach or suggest the comparing and determining elements of claim 26.

These arguments are referred to below as Argument A, Argument B, and Argument C, respectively.

Claim 1 of the Application recites:

> 1. A computer implemented method for processing prescription data representing a plurality of prescription drugs, said method comprising the steps of:
>
> arranging received prescription data that corresponds to a first prescription drug into a new record of a predetermined format containing an identifier for identifying said patient and further containing a first name of said first prescription drug;
>
> accessing a plurality of pre-stored records of said predetermined format, each pre-stored record containing information on a plurality of prescription drugs previously prescribed for respective patients;
>
> comparing said identifier in said new record with each identifier located in the pre-stored records to find a matching pre-stored record associated with said patient;
>
> comparing said first name of said first prescription drug with a second name of a second prescription drug located in the found matching pre-stored record; and
>
> identifying said first prescription drug as a new therapy start for said patient if said first name is not substantially identical to said second name.

Claim 26 of the Application recites:

> 26. A computer implemented method for processing prescription data using a plurality of pre-stored prescription data records, each of which comprises a patient identifier identifying a patient and a drug identifier identifying a drug being prescribed to the identified patient of the respective record, the method comprising:
>
> receiving a first prescription data record comprising a patient identifier identifying a first patient and a drug identifier identifying a drug being prescribed to the first patient;
>
> comparing the patient identifier of the first prescription data record to the patient identifier of each of the plurality of pre-stored prescription data records to find all pre stored prescription data records having a patient identifier matching the patient identifier of the first prescription data record;
>
> identifying all the illnesses treatable by the drug being prescribed of the first prescription data record;

for each matching pre-stored prescription data record, identifying all the illnesses treatable by the drug being prescribed of the respective pre-stored prescription data record; and

determining whether the drug being prescribed of the first prescription data record is a therapy switch based on the illnesses treatable by the drug being prescribed of the first prescription and the illnesses treatable by any drug being prescribed of any of the matching pre stored prescription data records.

In the Examiner's Answer, dated March 9, 2004, the Examiner provided responses to the arguments above. Applicant submits this Reply Brief to address the Examiner's responses.

REPLY TO EXAMINER'S RESPONSES

In the Examiner's responses to Arguments A and B, the Examiner refers to several tests performed by the Portwood system. Specifically, the Examiner refers to Portwood's comparison of prescription data (which the Examiner asserts includes patient name, drug name, unit and strength, duration and dosage of the prescribed drug, and a patient identification code) with patient data and prescription data to perform tests on the prescription including underdosing, overdosing, length of therapy, drug interaction, and prior adverse reaction tests. (Examiner's Answer, pp. 22-23) The Examiner then asserts that these tests suggest the comparing and identifying elements of claim 1.

The Applicant respectfully disagrees. As shown above, the comparing and identifying elements of claim 1 of the Application recite comparing a name of a drug from a new prescription record for a patient with a name of a drug from a pre-stored prescription record for the same patient and identifying the drug from the new record as a new therapy start if the name of that drug is not substantially identical with the name of the drug from the pre-stored record.

None of the tests performed by Portwood referred to by the Examiner disclose or suggest identifying a new therapy start, as recited in claim 1 of the Application, for several reasons. First, each of these tests performed by Portwood compares a currently prescribed drug to information which cannot reveal whether the currently prescribed drug is a new therapy start, *e.g.*, a drug not previously prescribed for that patient. Second, Portwood provides no motivation for modifying any of these tests to identify a new therapy start.

The underdosing, overdosing, and length of therapy tests of Portwood compare a currently prescribed drug to generic pharmaceutical data to determine whether the current prescription falls within industry recommended dosage and duration guidelines. (see Portwood Cols. 10-14). The drug interaction test of Portwood compares the drugs currently being prescribed with pharmaceutical data to determine if any currently prescribed drug will cause an unacceptable reaction with any other currently prescribed drug. (see Portwood Col. 15, lines 6-60). Thus, none of these tests can possibly identify a drug currently prescribed for a patient as a new therapy start, because all of these tests compare current prescriptions to generic pharmaceutical data that is not specific to any patient, rather than information on drugs previously prescribed for the same patient.

The prior adverse reaction test of Portwood compares a drug currently prescribed for a patient with reports of adverse drug reactions from the same patient. (see Portwood Col. 15, line 61 to Col. 16, line 10). This test also cannot identify a currently prescribed drug as a new therapy start because the test is restricted to comparing the current drug prescription with information regarding drugs to which the patient has reported an adverse reaction. A negative result from this test of Portwood, *e.g.*, no match found between the current drug prescription and

reports by the patient of prior adverse reactions, means only that there is no report by the patient of a previous adverse reaction to the currently prescribed drug. A negative result does not mean that the currently prescribed drug was never previously prescribed for the patient since a negative result could be due to the patient having previously taken the currently prescribed drug without having reported any adverse reaction to it.

Thus, as shown above, the type of information against which a current drug prescription is compared by the system of Portwood in the tests referred to by the Examiner cannot allow the system of Portwood to identify a currently prescribed drug as a new therapy start.

Furthermore, Portwood provides no motivation for modifying any of the tests referred to above to identify a current prescription as a new therapy start. A stated goal of the system of Portwood is to ensure the integrity of drugs prescribed for a patient. (See Portwood, Col. 1, lines 7-12). Identifying a currently prescribed drug as a new therapy start, as recited in claim 1, would not be useful for achieving this goal of Portwood since simply identifying a drug as one not having been previously prescribed for a patient does not reveal any useful information regarding the integrity of the drug prescription, *e.g.*, whether the prescription falls within industry guidelines for dosage and duration, whether one prescribed drug will cause an unwanted reaction with another prescribed drug, or whether the patient previously reported an adverse reaction to the drug. Thus, identifying a currently prescribed drug as a new therapy start is irrelevant to the system of Portwood, and so, Applicant respectfully submits that there is no motivation within the Portwood for performing such an identification or modifying any of the tests of Portwood referred to by the Examiner to perform such an identification.

In the Examiner's response to Argument C, the Examiner refers to the same tests of Portwood as discussed above and asserts that these tests suggest the comparing and determining elements of claim 26. Applicant respectfully disagrees for similar reasons as discussed above for claim 1.

First, the type of information against which the tests of Portwood referred to by the Examiner compare a current prescription cannot reveal a therapy switch, as recited by claim 26. The determination of whether a currently prescribed drug is a therapy switch (*e.g.*, a drug capable of treating an illness that a drug previously prescribed for the patient is also capable of treating), as recited in the comparing and determining elements of claim 26 above, involves a comparison related to the currently prescribed drug and all drugs previously prescribed for the same patient. However, as mentioned above, the underdosing, overdosing, length of therapy, and drug interaction tests of Portwood involve a comparison related to drugs currently prescribed for a patient and generic pharmaceutical data for those same currently prescribed drugs, and not any drugs previously prescribed for the patient. The prior adverse reaction test involves a comparison related to a drug currently prescribed for a patient and only drugs previously prescribed for the patient for which an adverse reaction was reported, and not all drugs previously prescribed for the patient. Therefore, none of these tests performed by Portwood referred to by the Examiner can determine whether a currently prescribed drug is a therapy switch, as recited in claim 26.

Furthermore, Portwood provides no motivation for making such a determination or modifying the tests of Portwood referred to by the Examiner to make such a determination. As mentioned above in connection with claim 1, a goal of the system of Portwood is to ensure the

integrity of drugs prescribed for a patient. Simply determining whether a drug currently prescribed for a patient treats an illness that a drug previously prescribed for the same patient also treats, without providing any information on the integrity of the current prescription (*e.g.*, whether the patient previously had an adverse reaction to the currently prescribed drug), does not further any goal of the system of Portwood and is not relevant to that system. Thus, Applicant respectfully submits that there is no motivation within the Portwood for determining whether a currently prescribed drug is a therapy switch, as recited in claim 26, or modifying any test of Portwood referred to by the Examiner to achieve such a determination.

For at least the reasons above, Applicant respectfully submits that Portwood fails to teach the elements of claims 1 and 26 of the Application, discussed above, and therefore, claims 1 and 26 are patentably distinct over Portwood. Furthermore, since claims 1 and 26 are representative of all pending claims, Applicant respectfully submits that claims 1-49 of the Application are patentable over Portwood. Therefore, Applicant respectfully submits that the Examiner's

rejection of all pending claims of the Application should be overturned and that all pending claims of the Application be allowed.

The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to the undersigned attorney's Deposit Account No. 02-4270.

Respectfully submitted,

Dated: May 10, 2004

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Frederick Yu

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REQUEST FOR ORAL HEARING BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Docket Number (Optional)
3207/22US

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Typed or printed name Frederick Yu, Reg. No. 45,251

In re Application of
William M. Kleinfelter

Application Number	Filed
09/348,774	July 7, 1999

For PRESCRIPTION DATA PROCESSING SYSTEM...

Art Unit	Examiner
3626	Robert W. Morgan

Applicant hereby requests an oral hearing before the Board of Patent Appeals and Interferences in the appeal of the above-identified application.

The fee for this Request for Oral Hearing is (37 CFR 1.17(d)) $ 290.00

☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ _____

☑ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.

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☐ A petition for an extension of time under 37 CFR 1.136(b) (PTO/SB/23) is enclosed. For extensions of time in reexamination proceedings, see 37 CFR 1.550.

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I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☑ attorney or agent of record. Registration number 45,251

☐ attorney or agent acting under 37 CFR 1.34(a). Registration number if acting under 37 CFR 1.34(a). _____

Signature

Frederick Yu
Typed or printed name

212-895-2000
Telephone number

May 10, 2004
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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